

REMARKS

Restriction

The following is Applicants' response to Examiner's restriction requirement set forth in the Office Communication dated September 21, 2007 (Restriction Requirement). To be completely responsive to the Office Action, and without acquiescing in the propriety of the restriction requirement, Applicants elect, with traverse, to pursue Group I (claims 1-14, 16, and 20), drawn to a method for identifying an effective agent comprising detecting a detectable substance in cell culture.

The MPEP (at 809.02(a)) indicates that in the case of a species election, the Examiner should take the following actions

(A) Identify generic claims or indicate that no generic claims are present. See MPEP § 806.04(d) for definition of a generic claim.

(B) Clearly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, to which claims are to be restricted. The species are preferably identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, respectively. In the absence of distinct figures or examples to identify the several species, the mechanical means, the particular material, or other distinguishing characteristic of the species should be stated for each species identified. If the species cannot be conveniently identified, the claims may be grouped in accordance with the species to which they are restricted. Provide reasons why the species are independent or distinct.

(C) Applicant should then be required to elect a single disclosed species under 35 U.S.C. 121, and advised as to the requisites of a complete reply and his or her rights under 37 CFR 1.141.

The Restriction Requirement states (at page 4, fourth full paragraph)

Applicant is therefore advised to elect a single target gene, antisense sequence or inhibitory agent, cell culture type, reporter gene, plasmid or viral vector, promoter for the elected construct, gene to be incorporated into the elected promoter/reporter construct, treatable condition as well as electing on immature or mature form of target protein. (Emphases in the original)

Applicants do not understand the advisement. If intended as a species requirement, no generic claim is identified, no guidance is provided as to which claims are affected, and no statement is provided as to rights under 37 CFR 1.141. The Restriction Requirement provides a list of inventions (Groups I-VIII) on page 2, which Applicants assume to be a complete list of the Examiner's determination of the inventions. Applicants' representative discussed the Restriction Requirement with the Examiner on October 26, 2007, requesting clarification. The Examiner indicated that at least for claim 4 (with respect to a detectable substance gene) and claim 12 (with respect to promoter), a species election was intended. In view of the complete list of inventions and the discussion with the Examiner, Applicants assume that the advisement is intended as a requirement for a species election. If a species election was intended, Applicants select the following species for prosecution on the merits;

- promoter/detectable substance gene reporter: CYP8B1;
- agent: small molecule;
- reporter gene: Renilla luciferase;
- vector: adenovirus;
- promoter: CMV promoter; and
- cell culture: human hepatoblastoma cell line.

Applicants further submit that claim 1 is generic.

Applicants believe that this response is in compliance with and complete with respect to the restriction requirement.

Upon allowance of a claim to an elected species, Applicants reserve the right to rejoin additional species upon allowance of a generic claim.

Applicants respectfully traverse the Restriction of claim 19 (Group IV). Claim 19 depends from claim 1, and adds an additional feature to the invention of claim 1. A search of the subject matter related to claim 1 will necessarily encompass the subject matter of claim 19. Accordingly, no additional burden is placed on the Examiner by examination of claim 19 and Applicants therefore respectfully request that the restriction with respect to Group IV be withdrawn and claim 19 joined with elected Group I.

Claim 18 has been amended to reference a CYP7A1 promoter or a CYP8B1 promoter. Reference to NFkB has been deleted. Accordingly, Applicants submit that, as amended, claim 18 properly belongs in elected Group I and request inclusion of the claim in Group I.

Amendment

Entry of this Amendment is respectfully requested. Applicants note that upon entry of this Amendment, claims 1-14 and 16-20 will be pending in the present application. Claims 15, 17, and 21-67 have been canceled without prejudice and Applicants reserve the right to pursue canceled subject matter in further applications.

To expedite prosecution, the claims have been amended to cancel features of claims and claims related to a method for identifying an agent effective for inhibiting farnesoid X receptor and/or employing an NFkB promoter/detectable substance gene reporter. The pending claims are therefore drawn to a method for identifying an agent effective at inhibiting short heterodimer protein (SHP). Claims 1, 16, and 18 have been amended to clarify the claimed invention and to specify a CYP7A1 promoter/detectable substance gene reporter or a CYP8B promoter/detectable substance reporter gene. Support for the amendment is found throughout the specification, for example at paragraph 168 and Examples 2-4. Claim 9 has been amended merely to clarify the language.

No new matter is believed to be introduced by the claim amendment.

Applicants believe the Amendment places the claims in condition for substantive examination and allowance, which action is respectfully requested.

CONCLUSION

A five-month Petition for Extension of Time and authorization to charge the petition fee is enclosed herewith. No additional fees are believed to be due. However, if such a fee is due or a credit is owed, please make them to our Deposit Account No. 08-0219, referencing attorney docket number 0036119.00159US4.

The Examiner is encouraged to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,

Dated: March 21, 2008

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